DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 4, 2014

Minimally Invasive Devices Incorporated
Ms. Trudie L. Seeger
Vice President of Regulatory, Quality and Clinical Affairs
1275 Kinnear Road
Columbus, Ohio 43212

Re: K141272
Trade/Device Name: FloShield 10mm Endoscopic Cannula and Blunt Obturator
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 26, 2014
Received: August 27, 2014

Dear Ms. Seeger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141272

Device Name
FloShield 10mm Endoscopic Cannula and Blunt Obturator

Indications for Use *(Describe)*

The reusable FloShield 10mm Endoscopic Cannula and Blunt Obturator is an access device indicated for use with a disposable 8.5 — 13mm Cannula Seal manufactured by Applied Medical to provide a passageway for the introduction of endoscopic instruments in general laparoscopic procedures. The access device is compatible with the da Vinci Si Surgical System.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Minimally Invasive Devices Inc
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510(k) Summary
(21 CFR §807.92(c))

510(k) Number:	K141272
Submitter:	Minimally Invasive Devices, Inc. 1275 Kinnear Road Columbus, Ohio 43212
Contact:	Trudie L. Seeger, Ph.D. V.P., Regulatory/Quality/Clinical Affairs Telephone: 614-484-5036 Fax: 614-484-5034 E-mail: tseeger@midsurgical.com
Date Summary Prepared:	08 Aug, 2014
Device Trade Name:	FloShield 10mm Endoscopic Cannula and Blunt Obturator
Common Name:	Cannula and Obturator
Classification Name:	Laparoscope, General & Plastic Surgery (21 CFR §876.1500)
Product Code:	GCJ
Predicate Devices:	Karl Storz 10mm Reusable Trocar with Hasson Style Obturator (K943713, K943897) daVinci Si 8.5mm Reusable Accessory Cannula (K122532) daVinci Si 10mm Reusable Accessory Cannula (K122532)

Device Description:

The FloShield 10mm Endoscopic Cannula and Blunt Obturator are re-usable stainless steel endoscopic instruments delivered non-sterile to the hospital where it is cleaned, sterilized (steam / moist heat), and assembled prior to surgery. The FloShield 10mm stainless steel Cannula mates with a disposable Applied Medical 8.5 – 13mm Cannula Seal manufactured and supplied sterile by Applied Medical. The stainless steel Cannula has the ability to connect to a standard male luer fitting, via the female luer that is present on the Cannula. The device will accommodate a standard 8.5mm to 10mm endoscopic instrument (outside diameter). The stainless steel Obturator is a Hasson style, blunt tip obturator that facilitates the insertion of the cannula through an incision site.

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Intended Use/Indications for Use:

The reusable FloShield 10mm Endoscopic Cannula and Blunt Obturator is an access device indicated for use with a disposable 8.5 – 13mm Cannula Seal manufactured by Applied Medical to provide a passageway for the introduction of endoscopic instruments in general laparoscopic procedures. The access device is compatible with the da Vinci Si Surgical System.

Comparison to Predicate Devices:

The FloShield 10mm Endoscopic Cannula and Blunt Obturator has the same design, materials and intended use as the Karl Storz 10mm Reusable Trocar with Hasson Style Obturator (K943713, K943897), the daVinci Si 10mm Reusable Accessory Cannula (K122532) and the daVinci Si 8.5mm Reusable Accessory Cannula (K122532).

Technological Characteristics:

The technological characteristic of the FloShield 10mm Endoscopic Cannula and Blunt Obturator are very similar to the predicate devices. All cannulas are stainless steel and reusable. The stainless steel Cannula has the ability to connect to a standard male luer fitting, via the female luer that is present on the Cannula. The device will accommodate a standard 8.5mm to 10mm endoscopic instrument (outside diameter). The Karl Storz 10mm Reusable Trocar has an additional stopcock valve in its Luer fitting and has a reusable gas and instrument seal. The FloShield 10mm Endoscopic Cannula, daVinci Si 8.5mm Reusable Accessory Cannula (K122532), and the daVinci 10mm Reusable Accessory Cannula all use the disposable 8.5 – 13mm Cannula Seal manufactured and supplied sterile by Applied Medical. The obturators function identically (i.e., facilitates the insertion of the cannula through an incision site) with the only difference being that the Karl Storz Hasson Style Obturator is a conical blunt obturator and the FloShield Blunt Obturator and the da Vinci Blunt Obturator are full blunt Hasson obturators. FloShield Blunt Obturator and the Karl Storz Hasson Style Obturators are made of stainless steel and the daVinci Blunt Obturator is made of plastic all devices will accommodate a standard 8.5mm to 10mm endoscopic instrument (outside diameter).

Performance Testing:

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The performance and functional testing of the FloShield 10mm Endoscopic Cannula and Blunt Obturator included tests to verify its ability to create and maintain a port of entry during simulated laparoscopic surgery, its ability to maintain pneumoperitoneum during the course of surgery and comparable functional characteristics to the predicates (Leak Resistance, Insufflating Flow Rates, Insertion and Removal Force, Snap Retention).

Sterilization validation for reusable devices was successfully performed in accordance with ISO 17665: 2006 Sterilization of Healthcare Products – Moist Heat – Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices and ANSI/AAMI ST81:2004 (R2010): Sterilization of Medical Devices – Information to be provided by the manufacturer for the processing of re-sterilizable medical devices.

Conclusion Drawn from Tests and Analyses:

The intended use and performance parameters of the FloShield 10mm Endoscopic Cannula and Blunt Obturator are similar or equivalent to the characteristics of the Karl Storz 10mm Reusable Trocar with Hasson Style Obturator (K943713, K943897), the daVinci Si 8.5mm Reusable Accessory Cannula (K122532), and the daVinci Si 10mm Reusable Accessory Cannula (K122532) as determined in Section 12.0 of this Premarket Notification (510(k)) submission.